

# PATENT COOPERATION TREATY

JPF  
CYM  
KSL

From the INTERNATIONAL SEARCHING AUTHORITY

To:  
J. PETER FASSE  
FISH & RICHARDSON, P.C.  
225 FRANKLIN STREET  
BOSTON, MA 02110-2804

RECEIVED

MAY 16 2005

FISH & RICHARDSON, P.C.  
BOSTON OFFICE

PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 00786-607WO1	Date of mailing (day/month/year)
International application No. PCT/US05/03158	International filing date (day/month/year) 31 January 2005 (31.01.2005)
Applicant THE GENERAL HOSPITAL CORPORATION	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.  
  
 Filing of amendments and statement under Article 19:  
 The applicant is entitled, if he so wishes, to amend the claims or the description of the invention (see Rule 46):  
 When? The time limit for filing such amendments is normally 3 months from the date of transmittal of the international search report.  
  
 Where? Directly to the International Bureau of WIPO, 34, Avenue des Caïmans, 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35  
  
 For more detailed instructions, see the notes on the accompanying sheet.
2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
  - ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
  - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4. Reminders  
 Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.  
 The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.  
 Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.  
 In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.  
 See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer James Seidick Telephone No. 703-308-0661
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Form PCT/ISA/220 (January 2004)

Docketed By Due Date Initials	Patent Secretary (See notes on accompanying sheet)
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Docketed By Practice Systems

Search Rep. RSPN 71208

Initials: [Signature]

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:  
J. PETER FASSE  
FISH & RICHARDSON, P.C.  
225 FRANKLIN STREET  
BOSTON, MA 02110-2804

## PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 00786-607WO1	Date of mailing (day/month/year) <b>12 MAY 2005</b>
International application No. PCT/US05/03158	International filing date (day/month/year) 31 January 2005 (31.01.2005)
Applicant THE GENERAL HOSPITAL CORPORATION	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.  
  
 Filing of amendments and statement under Article 19:  
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):  
  
 When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.  
  
 Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35  
  
 For more detailed instructions, see the notes on the accompanying sheet.
2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
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  - ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
  - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
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 Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.  
  
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 See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450  Facsimile No. (703) 305-3230	Authorized officer  James Seidleck  Telephone No. 703-308-0661
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Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 00786-607WO1	<b>FOR FURTHER ACTION</b>		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US05/03158	International filing date ( <i>day/month/year</i> ) 31 January 2005 (31.01.2005)	(Earliest) Priority Date ( <i>day/month/year</i> ) 30 January 2004 (30.01.2004)	
Applicant THE GENERAL HOSPITAL CORPORATION			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the Report**

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box No. II)

3. ☐ Unity of invention is lacking (See Box No. III)

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. \_\_\_\_\_

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☒ none of the figures is to be published with the abstract.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/03158

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(7) : C08F 120/32, 283/10; C08L 71/02, 79/02 US CL : 525/162, 187, 327. 3, 540 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 525/162, 187, 327. 3, 540 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	US 6,780,428 B2 (RANGER et al) 24 August 2004 (24.08.2004), col. 3, lines 43-45, col. 4, lines 45-46 and 57, col. 5, lines 19-42, col. 6, lines 31-59	1-3, 10-11 and 13
X	US 6,440,743 B1 (KABANOV et al) 27 August 2002 (27.08.2002), col. 3, line 55, col. 13, lines 40-54, col. 43, line 10	1-3, 13
X	US 6,288,197 B1 (YOUNGS et al) 11 September 2001 (11.09.2001), col. 2, lines 46-67, col. 3, lines 1-28, col. 4, lines 24-67	1-3
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 05 May 2005 (05.05.2005)		Date of mailing of the international search report <b>12 MAY 2005</b>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer James Seidleck Telephone No. 703-308-0661 Jean Proctor Paralegal Specialist

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US05/03158

Continuation of B. FIELDS SEARCHED Item 3:

WEST: core-shell copolymer or dendrimer or hyperbranched copolymer; grafted; active terminal hydrogen or terminal hydroxyl group or terminal amine group, or terminal thiol adj group

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:  
J. PETER FASSE  
FISH & RICHARDSON, P.C.  
225 FRANKLIN STREET  
BOSTON, MA 02110-2804

Date of mailing  
(day/month/year)

12 MAY 2005

Applicant's or agent's file reference

00786-607WO1

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

PCT/US05/03158

International filing date (day/month/year)

31 January 2005 (31.01.2005)

Priority date (day/month/year)

30 January 2004 (30.01.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C08F 120/32, 283/10; C08L 71/02, 79/02 and US Cl.: 525/162, 187, 327, 3, 540

Applicant

THE GENERAL HOSPITAL CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

James Seidleck

Telephone No. 703-308-0661

*Jean Proctor*  
Patent Paralegal Sr.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/03158

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US05/03158

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 4-9, 12, 14-36	YES
	Claims 1-3, 10-11, 13	NO
Inventive step (IS)	Claims 4-9, 12, 14-36	YES
	Claims 1-3, 10-11, 13	NO
Industrial applicability (IA)	Claims 1-36	YES
	Claims NONE	NO

**2. Citations and explanations:**

Claims 1-3, 10-11, 13 lack novelty under PCT Article 33(2) as being anticipated by RANGER et al U.S. Patent 6,780,428.

RANGER discloses star-shape polymers having an inner core and an outer shell. The inner core comprises a hydrophobic vinyl compound such as (alkyl)acrylate and (alkyl)acrylamide and derivatives. The outer shell is obtained from the polymerization of hydrophilic vinyl compounds including a vinyl terminated polyethylene glycol, N-vinyl-2-pyrrolidone, N-isopropyl acrylamide and their related derivatives, column 5, lines 19-39. Claimed hyperbranched polymer having core/shell structure and having an active hydrogen-containing group on the outer shell segment is readable in RANGER's invention.

Claims 1-3 and 13 lack novelty under PCT Article 33(2) as being anticipated by KABANOV et al U.S. Patent 6,440,743.

KABANOV discloses star block copolymer having more than two polymer segments linked to a single center, col. 3, lines 45-60 and col. 4, lines 1-5. The star polymer can be used in Gene therapy, col. 10, lines 58-60 and col. 11, lines 34-67. The diamine-linked pluronic copolymer of formula (XVII), column 13, lines 40-55 and col. 14, lines 21-30 is readable in applicants' claims.

Claims 1-3 lack novelty under PCT Article 33(2) as being anticipated by YOUNGS et al U.S. Patent 6,288,197.

YOUNGS discloses dendrimer copolymer comprising a core segment and the dendritic branches with terminal NH<sub>2</sub> groups, Figure 1, col. 4, lines 24-67, col. 5, line 33 and column 15, lines 42-54.

Claims 4-9, 12, 14-36 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a hyperbranched polymer having core-shell structure wherein an inner core comprises a network of covalently bound molecular chains comprising ether linkage, the two heteroatoms are each oxygen atoms, the two oxygen atoms are spaced apart by at least four atoms.

Claims 1-36 meet the criteria set out in PCT Article 33(4), and thus has industrial applicability because the subject matter claimed can be made or used in industry.



## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

#### What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

**When ?** Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

**How ?** Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

**The amendments must be made in the language in which the international application is to be published.**

#### What documents must/may accompany the amendments ?

##### **Letter (Section 205(b)):**

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

**The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.**